B/C --33. The method of claim 34 wherein the nomegestrol acetate is administered at a dose of 2.5 mg per unit dosage.--

REMARKS

Reconsideration of this application is requested in view of the amendments to the specification and claims and the remarks presented herein.

The claims in the application are claims 21 to 33, all other claims having been cancelled.

Claims 1, 2, 4 and 7 were rejected under 35 USC 112, first paragraph, as the Examiner deemed the expression "equine conjugated estrogen" as being of unknown breadth and objected to the terms "estrogenic component" and "progestative component" as being unduly broad.

Applicants respectfully traverse this ground of rejection since it is believed that the amended claims properly define the invention. The term "equine conjugated estrogen" has been changed to the more correct translation of "conjugated equine estrogen". Conjugated equine estrogens are natural estrogens that are present in the blood in the form of glucuroconjugated and sulfoconjugated estrogens. The term is well known as can be seen from the Conard et al reference which uses the same term in the Abstract. It is

deemed that the expression "estrogenic component" and "the progestative component" are properly supported by the application and these types of steroid compounds are well known to those skilled in the art and there is not undue breadth in the claims. Therefore, withdrawal of this ground of rejection is requested.

Claims 3, 5 to 7 and 10 were rejected under 35 USC 112 as failing to properly define the invention. The Examiner objected to the terms "in particular" and "preferably" as set forth in the claims and it is believed that the amended claims are free of these objections since these terms do not appear in the present claims. Therefore, withdrawal of this ground of rejection is requested.

Claims 1, 2, 4, 5, 8 to 10, 16 and 18 to 20 were rejected under 35 USC 102 as being anticipated by the Sitruk-Ware reference or as being anticipated by the Conard et al reference. Claims 1, 2, 4 to 10 and 16 to 20 were rejected under 35 USC 103 as being obvious over the Conard et al reference. The Examiner has stated that the Sitruk-Ware reference discloses oral hormonal compositions wherein the combination of estrogen-progestogen are used for simultaneously delivering a progestogen component and an estrogen component. The Conard et al reference, according to the Examiner, teaches the instant compositions as being taught by the prior art.

Applicants respectfully traverse these grounds of rejection since it is believed that the prior art neither anticipates nor

renders obvious Applicants' compounds. The Sitruk-Ware reference indicates in its summary that "derivatives of 19-nor-progesterone such as nomegestrol acetate or ST 1435 are not used as oral contraceptives but are being evaluated through parenteral administration e.g. implants or transdermal systems". In contrast thereto, the present claims which are all method claims, are drawn to the oral administration of the derivative of 19-nor-progesterone and the estrogenic component. Therefore, the reference neither anticipates nor renders obvious Applicants' invention.

With respect to the Conard et al reference, the amount of estradiol combined with nomegesterol acetate is only administered for a period of 14 consecutive days after which, an amount of estradiol alone is given for 10 consecutive days and before the administration of the placebo for the last 7 days. The use of the estradiol/nomegestrol acetate constitutes a part of a trisequential replacement hormonal treatment. In the present claims, the combination of estrogen/progesterone derived from 19-nor-progesterone is the only composition used in a continuous or intermittent fashion for 21 to 25 days per month with the intention to correct estrogenic deficiencies in natural or artificial menopause or to stop ovulation in women during their period of ovarian activity. This is the main difference between the Conard et al reference and Applicants' invention. Therefore, the references neither anticipate nor render obvious Applicants' invention and withedrawal of these grounds of rejection is

requested.

In view of the amendments to the specification and claims and the above remarks, it is believed that the claims clearly point out Applicants' patentable contribution. Therefore, favorable reconsideration of the application is requested.

Respectfully submitted,
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CAM:ds
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